

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 21

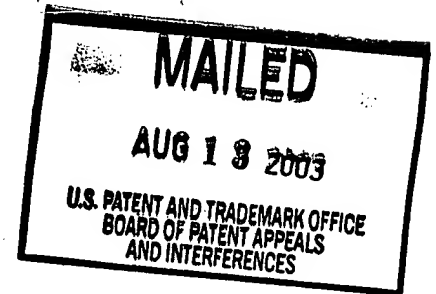
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THOMAS L. STEINEMANN, IVORY A. REIS,
LOUIS M. FINK, HARRY H. BROWN and
RICHARD A. MARLAR

Appeal No. 2002-0869
Application No. 08/580,384

ON BRIEF



Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

ON REMAND TO THE EXAMINER

This is an appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 22-29, which are all of the claims pending in this application.

Claim 22 is illustrative of the claims on appeal and reads as follows:

22. A method of reducing intraocular inflammation comprising the administration of a pharmacologically effective dose of protein C to reduce said intraocular inflammation to an individual having said inflammation.

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The prior art references relied upon by the examiner are:

Galin	4,240,163	Dec. 23, 1980
Bang et al. (Bang)	5,151,268	Sept. 29, 1992
Esmon et al. (Esmon)	5,147,638	Sept. 15, 1992
Stocker et al. (Stocker)	4,489,403	July 18, 1989

Iverson, D.A., "Inhibition of Intraocular Fibrin Formation Following Infusion of Low-Molecular Weight Heparin During Vitrectomy," Arch. Ophthalmol., Vol. 109, pp. 405-409 (1991)

Grounds of Rejection

Claims 22-27 stand rejected under 35 U.S.C. § 103(a) as obvious over Galin or Iverson in view of Bang and Esmon.

Claims 28-29 stand rejected under 35 U.S.C. § 103(a) as obvious over Galin or Iverson in view of Bang and Esmon in further view of Stocker.

We vacate these rejections and remand the application to the examiner for action consistent with the discussion herein.

DISCUSSION

Our consideration of the record leads us to conclude that this case is not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and take appropriate action.

In making our determination of the course of action in the present appeal we have taken into consideration the appeal in copending Serial No. 08/696,698 (Appeal No. 2001-1685, attached). As a consequence of our review, we make the

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determinations which follow.

35 U.S.C. § 103

Claims 22-27 stand rejected under 35 U.S.C. § 103(a) as obvious over Galin or Iverson in view of Bang and Esmon. Claims 28-29 stand rejected under 35 U.S.C. § 103(a) as obvious over Galin or Iverson in view of Bang and Esmon in further view of Stocker. We vacate these rejections and remand the application to the examiner for action consistent with the discussion herein.

Remand

Claim 22 of the present application is directed to a method of reducing intraocular inflammation comprising the administration of a pharmacologically effective dose of protein C to reduce said intraocular inflammation to an individual having said inflammation. Copending application Serial No. 08/696,698 (Appeal No. 2001-1685) included claims to related subject matter directed to a method of reducing amounts of intraocular fibrin comprising the administration of a pharmacologically effective dose of Protein C as to reduce the amount of intraocular fibrin in an individual having elevated levels of intraocular fibrin. In the copending application, we reversed the rejection of the examiner. The rejection in that case was based upon several references in common with the rejection of the claims in the present application, particularly Iverson and Bang, and appears to have turned on a similar issue, that of expectation of success

in substituting protein C for heparin in the eye.

Appellants argue that because the ocular area is normally isolated from the blood stream by the blood-aqueous barrier, a vascular phenomenon that may apply in other tissues does not necessarily apply to the ocular environment. Brief, page 10. It is argued that there are many reasons why a cascade reaction may be disrupted in a tissue specific manner such as the presence of tissue specific inhibitors or the tissue specific absence of a required cofactor. In particular, appellants argue, the effectiveness of protein C in reducing inflammation in the eye has not been demonstrated prior to the present invention. Brief, pages 10-11.

In copending application Serial No. 08/696,698 (Appeal No. 2001-1685) appellants argued that a person of ordinary skill in the art would not have had a reasonable expectation that protein C would have a pharmacological effect in the eye. In support of this position appellants argued that "delivery of therapeutic pharmaceuticals to the eye is not a trivial matter. In many instances, systemically administered drugs do not reach the eye in therapeutic levels; and ... [m]any drugs, if systemically administered in large concentrations to achieve a desired result in the eye, would result in serious systemic dysfunction, side effects and possibly death."

Upon return of the application to the examiner, it is recommended that the examiner take a step back and review the record in copending application Serial No. 08/696,698 (Appeal No. 2001-1685) with respect to the issue of expectation of success. In addition, appellants should consider making of record in the present case the prior

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art references Snyder and Howard, submitted with respect to the issue of expectation of success in the copending application to support their position with evidence.

In addition, appellants argue in the current record that Esmon does not teach the presence of TNF in the ocular environment, and provides no evidence that the biochemical cascade of events associated with inflammation and TNF occurs in either the aqueous or vitreous humor of the eye. Brief, page 9. Upon return of the application to the examiner, if the examiner determines it appropriate to maintain the obviousness rejection in view of the currently cited references, the examiner should make of record evidence confirming that the biochemical cascade of events associated with inflammation and TNF occurs in the eye.

CONCLUSION

We vacate the rejections of claims 22-27 under 35 U.S.C. § 103(a) for obviousness over Galin or Iverson in view of Bang and Esmon, and of claims 28-29 under 35 U.S.C. § 103(a) for obviousness over Galin or Iverson in view of Bang and Esmon in further view of Stocker. Upon return of the application, the examiner should take a step back and review the record in copending appeal Serial No. 08/696,698 (Appeal No. 2001-1685) with respect to the issue of expectation of success and other matters consistent with the discussion herein.

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This application, by virtue of its "special" status, requires an immediate action.

Manual of Patent Examining Procedure (MPEP) § 708.01(d)(7th ed., July 1998).

VACATE and REMAND


DEMETRA J. MILLS
Administrative Patent Judge


ERIC GRIMES
Administrative Patent Judge


LORA M. GREEN
Administrative Patent Judge

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